Standards Overview

with Scott Colburn

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Hello, I'm Scott Colburn, the Director of the Standards Management staff in FDA's Center for Devices and Radiological Health or CDRH. Today I will discuss how standards became integral to the mission of CDRH and how they are used.
Standards give the agency flexibility and discretion to use standards other than those that we develop ourselves. Standards also build in a culture of collaboration that fosters consensus, consistency and predictability. At the FDA, standards have become an important part of the execution of the agency's mission.

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At the end of this module you will understand what is a standard, what it is not and what is a voluntary consensus standard. I will be giving you an overview of the key pieces of legislation that forms the basis of the US national standards strategy. I will discuss the evolution of standards utilization by FDA, as well as explain the different types of standards products that are published. Lastly, you will learn how standards are used in CDRH.

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The word standard calls to mind many definitions, but this presentation will focus on how FDA views standards in light of our regulatory authority. Specifically, the term standard or technical standard is found in the Food, Drug & Cosmetic Act or FD&C Act. This definition includes a common and repeated use of rules, conditions, guidelines or characteristics for products or related processes, production methods, and related management systems practices.

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The word standard can also include definitions, a classification system or components, a series of procedures to follow, specifications for sizes or dimensions, materials, performance, design or operations. Standards can be written for quality measures or describe amounts of materials. Standards can describe a process, a system, a service, a practice, or a specific product. And standards may be written to outline a specific test method, a sampling plan, or a way to measure size, strength, or other physical attribute.

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Throughout this presentation you will hear me refer to "voluntary consensus standards". A voluntary consensus standard is a standard developed or adopted by voluntary consensus standards bodies, both domestic and international.
Note that this type of standard is not developed by the Federal Government, but instead by a voluntary consensus standards body. It may be either a national or an international standards developing organization or SDO.

The definition includes a provision that the standard will be made available to all interested parties and that technical standards are also developed or adopted by voluntary consensus. Integral to the development of voluntary consensus standards is due process, which includes committee balance of membership, openness of committee proceedings, and an appeals mechanism.

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In 1995, Congress passed the National Technology Transfer and Advancement Act, or NTTAA, which directed Federal Agencies with respect to the use of private sector standards and conformity assessment of standards. This was signed into law in 1996 and grew out of the Department of Defense experience with regards to military specifications or MIL Specs.

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The Law specifically directed Agencies in the Executive Branch to begin using voluntary consensus standards, instead of government unique standards, where appropriate. The Law also encouraged Agencies to begin collaborating on voluntary consensus standards by participating during the standards development process and negotiating agency positions.

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The NTTAA brought civilian agencies like the FDA into the practice of using private sector standards instead of government unique standards.

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This slide includes a web link to the NTTAA legislation and discussions on how the legislation is interpreted and administered. A central location for standards in the U.S. is National Institute of Standards and Technology, or NIST.
A link to their site is on the slide.

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The Office of Management and Budget, or OMB, published Circular A-119 that established policies for Federal agencies to follow with regards to the development of voluntary consensus standards. It establishes policies on conformity assessment activities, provides definitions of commonly used terms such as "standards", and "voluntary consensus standards".

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The circular sets forth requirements for Agency participation on standards committees and working groups, which includes a reporting requirement to Congress on an annual basis. The circular also sets forth requirements for incorporation of standards into Agency regulations. When standards are used in CDRH, they are voluntary. The only exception is when a standard is incorporated by reference into regulation. When that occurs, the standard becomes mandatory.

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The goals of the circular include the elimination or reduction of government costs that would be incurred if agencies were to develop their own standards, to provide incentives for agencies to use standards that serve the National interests, to encourage long-term economic growth for the US, and to promote competition in the marketplace.

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As stated earlier in the presentation, the NTTAA directs Federal agencies to adopt or recognize standards that were created by private sector instead of creating proprietary non-consensus or government-unique standards. This law directs NIST to coordinate Federal, State, and local governments to have a greater reliance on voluntary consensus standards and decrease dependency on government-unique standards.

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This slide provides the links to the OMB Circular A 119 and to the NIST website that give further background on OMB and NIST's roles in implementing the US National Standards Strategy.

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Not only are standards important as tools that foster collaboration and consistency, standards are also useful in terms of saving both time and agency dollars. Standards engage collaboration across many types of stakeholders, such as manufacturers, consumers, patients, healthcare professional groups, etc. The issues or scope of the standard is often forward or leading edge and may lead to international harmonization.

The development and use of standards have been integral to the execution of the mission of FDA since its establishment. Standard-setting activities include matters such as the development of performance characteristics, testing methodology, manufacturing practices, product standards, scientific protocols, compliance criteria, ingredient specifications, labeling, or other technical or policy criteria. FDA staff has historically participated in a range of standard setting activities outside the Agency.

FDA approaches to standards and how it will utilize them is outlined in three key documents. Firstly, in the Code of Federal Regulations or CFR, FDA outlined its participation in outside standards setting activities. FDA published its position with regards to standards work and international harmonization in the Federal Register notice on October 11, 1995. Lastly, FDA wrote and published a Staff Manual Guide 9100.1 on the development and use of standards.

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In its FR Notice, FDA included a number of goals relating to standards and international harmonization. These goals were to utilize standards in a manner that would safeguard the US public health, to assure that consumer protection standards and requirements are met, to facilitate the availability of safe and effective products in the US market

place, to develop and utilize product standards, and to minimize or eliminate inconsistent standards internationally.

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The Staff Manual Guide establishes Agency-wide policies and procedures related to standards management to assure a unified approach to standards within the U.S. Food and Drug Administration. This guide does several things. It details the responsibilities of FDA employees for their participation in non-governmental organizations, including voluntary consensus standards bodies and intergovernmental international standards organizations engaged in the development of standards related to FDA regulated products. It describes the procedures related to the establishment of a Standards Management Program within FDA.

It describes the responsibilities of the Office of the Chief Scientist in managing the SMP and the responsibilities of the FDA Standards Committee in providing cross-Agency policy direction. And it details the procedures associated with executing these responsibilities. This Guide is based on and supplements the information provided by statute in the NTTAA, by OMB Circular A119, by regulation in 21 CFR 10.95, which is the Participation in outside standard-setting activities, and the FDA Policy on Standards titled, Policy regarding the development and use of standards with respect to international harmonization of regulatory requirements and guidelines.

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This slide shows some of the important concepts outlined in the Staff Manual Guide. Of note, FDA will recognize by reference either in their entirety or in part standards that are developed by Standard Developing Organizations. FDA will preferentially use international harmonized standards. When FDA releases guidance documents, these documents will cite standards wherever this is appropriate to do so and FDA also encourages sponsors of product applications to cite standards in their submissions. Lastly, FDA will incorporate voluntary consensus standards within its processes or regulations, when appropriate.

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Here are the references to the FDA FR Notice on Standards and Staff Manual Guide.

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The Medical Device Amendments of 1976 authorized the FDA to regulate all medical devices. It included a number of provisions with regards to standards and authorized the establishment of a performance standard for Class II devices.

It sets forth criteria to be followed in such standards which will ensure that the device is safe and effective and directs the FDA to provide for periodic evaluation of performance standards. It establishes procedures for the FDA to follow in developing and changing

such standards. It states that the FDA shall publish a notice in the Federal Register inviting any person, including any Federal agency, to submit an existing standard or an offer to develop such a standard. It states that if a standard, or offer to create a standard, is submitted to the FDA which FDA does not accept, the Agency shall publish in the Federal Register notice of that fact together with the reasons for not accepting the standard.

The Safe Medical Devices Act of 1990 revised the procedures for the FDA to establish or write performance standards for devices by requiring publication in the Federal Register and to allow for notice and comment on those performance standards the Agency developed.

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The FDA Modernization Act of 1997 significantly changed Section 514(c) of the FD&C Act, in that it allowed for the formal recognition of a standard, added a procedure for accepting a declaration of conformity and for conformity assessment. In the following slides I will go over each of the major revisions and discuss them.

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The term "recognize" or "recognition" is specific to Section 514(c) and to medical devices. It refers to FDA's identification of standards as appropriate for manufacturers of medical devices to declare conformance or to use the standard in a submission or other aspect to satisfy a requirement in the Act.

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In the next slides I have included key language from Section 514(c). This section states we will "by publication in the Federal Register, recognize all or part of an appropriate standard that has been established by a nationally or internationally recognized standard development organization, or SDO, for which a person may submit a declaration of conformity."

This section states that the use of standards is strictly voluntary and points to the use of standards in order to meet a premarket or other requirement under the Law.

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Section 514 goes further to clarify that if a person elects to use a standard, that the person shall provide a declaration of conformity with such standard. Along with the declaration, a person may use data, or information other than data to meet the requirement. This allows the submitter and FDA to assess the extent of conformity with the standard.

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Section 514 also includes a provision that allows the Agency to withdraw recognition of standards and this action is required to be published in the Federal Register. The

Agency commonly withdraws recognition of standards that are no longer published or no longer appropriate for meeting a requirement under this chapter.

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Lastly, Section 514(c) clarifies that along with a declaration of conformity, submitters should provide data or other information that explains how the device conforms to the standard or why the standard is applicable to the device in question.

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A Declaration of Conformity to an FDA-recognized consensus standard can be used when a submitter certifies that its device conforms to all of the requirements of an FDA-recognized consensus standard except for inapplicable requirements. In a Declaration of Conformity, the submitter may not deviate from the FDA-recognized consensus standard. The purpose of declaring conformance with an FDA-recognized consensus standard is to use such conformance to meet certain premarket requirements and reduce the amount of supporting data and information that are submitted to FDA. So a submitter who chooses to rely on an FDA-recognized consensus standard to meet a premarket submission requirement must, at the time of the submission, certify that the device is in conformity with the FDA-recognized consensus standard. This ensures that FDA can determine whether the submission meets applicable premarket requirements.

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Voluntary consensus standards can be a valuable resource for industry and FDA staff. The use of consensus standards can increase predictability, streamline premarket review, provide clearer regulatory expectations, and facilitate market entry for safe and effective medical products. They provide a consistent approach to certain aspects of the evaluation of device safety and effectiveness, such as testing methods, pass/fail performance criteria, and processes to address areas, such as risk management and usability. The use of consensus standards can also promote international harmonization.

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We have discussed how standards may be developed using a voluntary consensus process or a non-voluntary process. However, there are many types of standards in either category. These are described as basic standards, standards related to terminology and vocabulary, product specific standards that are vertical to a particular device or process standards that can be applied across device or product types. Performance standards set tolerances or specifications or outcomes for particular devices or products, and design standards outline a set of principles or approaches to be considered during a product's lifecycle.

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There are many types of standards products, but for the purposes of this discussion, I will go over the types of standards that are listed in the FDA recognized standards

database available on our website. These include vertical, test methods, material specifications, horizontal, national and international standards.

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Vertical standards are those that apply to a specific device or device groupings. These standards typically call out specific test methods or performance aspects of a specific grouping of devices. Note that vertical standards make reference to horizontal standards when appropriate. CDRH recognizes several hundred recognized vertical standards. An example of a vertical standard is listed on this slide.

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Standards may be written as specific test methods with a definitive test procedure that typically produces a test result. This result may then be used to assess compliance with a standard specification. CDRH recognizes approximately 100 test methods and an example is provided here.

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There are also standards that are written for material specifications. Material specifications typically include an explicit set of requirements to be satisfied by a material, product, system or service. The example provided on this slide is a test method that compares the burst or rupture strength of a sealant that is used on soft tissue.

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Horizontal standards can be applied across a wide range of devices and device types. These types of standards include biocompatibility, sterilization, materials, software and informatics. CDRH recognizes approximately 500 horizontal standards.

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National standards are those produced by standards developing organizations within the United States. The CDRH recognition database designates national standards in one of two ways, either by the standards developer or by the American National Standards Institute, or ANSI, followed by the national standards developing organization. An example is included on this slide.

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An international standard is one that has been developed by a harmonized standard developer such as the International Organization for Standardization or ISO or the International Electrotechnical Commission, or IEC. However, other standards-developing organizations may also be considered international based on the number of countries to which they are published.

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The American National Standards Institute has procedures for an American standards developer that wishes to adopt an ISO or IEC standard and this adoption can take the form of an identical national adoption, a modification in relation to the ISO or IEC standard, or a not equivalent to the ISO or IEC standard.

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Other types of standards products include standard practices, guides or guidelines. These types of products typically do not include normative requirements under the standard. But they may include a set or collection of information or options that do not necessarily recommend a specific course of action.

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No matter the type of standard product, CDRH believes that conformance with a recognized consensus standard can support a reasonable assurance of safety and/or effectiveness for many applicable aspects of medical devices. Their information submitted in a premarket submission with such standards should have a direct bearing on safety and effectiveness determinations made with regards to such submissions.

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One should always understand that the use of a consensus standard generally satisfies only one part of a premarket submission and that it may not, on its own, provide a sufficient basis for a regulatory decision. Most standards do not satisfy all the required elements of a submission. It is important to understand that FDA's recognition of a standard does not supersede other aspects of the FD&C Act and its implementing regulations for marketing or investigating medical devices in the US.

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Use of consensus standards to meet premarket submission requirements can help facilitate the premarket review process such as Traditional, Abbreviated, and Special Premarket Notifications, or 510(k)s, de novo classification requests, investigational device exemptions or IDEs, premarket approval applications or PMAs, product development protocol, or PDPs, humanitarian device exemptions, or HDEs, or Q submissions. In addition, standards may be used in Investigational New Drug, or IND, and Biologics License Applications or BLAs, for devices regulated as biological products by the Center for Biologics Evaluation and Research under section 351 of the Public Health Service (PHS) Act. Note that the standards only satisfy part of the requirements for CBER applications. In addition, submitters may choose to conform to applicable consensus standards or address issues relevant to approval or clearance in another manner.

Regardless of the decision a submitter ultimately makes about the use of consensus standards, submitters should make sure their premarket submissions contain all necessary information, as required by the FD&C Act and its implementing regulations.

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In 510(k) submissions, appropriate use of consensus standards can be effective in demonstrating individual aspects of substantial equivalence. Under such use, consensus standards will typically reduce the amount of documentation that a submitter needs to provide and may reduce FDA review time.

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Let's recap what we've covered. First, we defined the term standard and reviewed the different types of standards. We reviewed the key pieces of legislation that formed the basis of the U.S. National Standards Strategy. Finally, we discussed the evolution of standards and how they are used by FDA. I hope you found this presentation useful. Thank you.

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